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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/617,895	07/11/2003	Ryan P. Boucher	41914.465 / P0031798.155	4066
46333	7590	11/09/2009		
Medtronic			EXAMINER	
Attn: Noreen C. Johnson, IP Legal Department			YABUT, DIANE D	
2600 Sofamor Danek Drive				
Memphis, TN 38132			ART UNIT	PAPER NUMBER
			3734	
			MAIL DATE	DELIVERY MODE
			11/09/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/617,895	Applicant(s) BOUCHER ET AL.	
	Examiner DIANE YABUT	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 August 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/25/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/24/2009 has been entered.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 08/25/2009 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Objections

3. Claim 7 is objected to because of the following informalities: Line 6 reads "an inner" and should rather be --the inner--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 14-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claims 14-15 recite “through the lumen,” but is not clear as to which of either the outer elongate body lumen or the inner elongate body lumen of the catheter tube assembly the applicant is referring to. Also, claim 14 recites “the stylet is coupleable to the catheter body,” and similarly it is unclear as to which part of the catheter body – inner or outer – the stylet is coupleable to.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-2, 4-9, 11-12, and 14-15 are rejected under 35 U.S.C. 102(b) as being anticipated by **Fogarty et al.** (U.S. Patent No. **4,483,340**).

In regards to claims 1-2, 4, and 12 Fogarty et al. disclose a catheter body **24** defining an interior lumen, an expandable structure **20** having a distal end and carried by the catheter body and a substantially rigid stylet **30** having a proximal end and being

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sized and configured for passage through the lumen and adapted to straighten the expandable structure during deployment into an interior body region, the stylet being selectively insertable into and withdrawable from an interior of the expandable structure via the lumen without expanding the expandable structure (Figures 1-4).

In regards to claims 5 and 14-15, the proximal end **36** of the stylet is coupleable to the catheter body and it abuts against the distal end **22** of the expandable structure (Figure 4).

In regards to claim 6, the catheter body has an open distal end **22** configured to prevent movement of the stylet therethrough.

In regards to claims 7-8 the catheter tube assembly includes an outer elongate body **14** and an inner elongate body **24**, wherein the expandable structure **20** has a proximal end that is coupled to a distal end of the outer elongated body **14** and a distal end coupled to a distal end **22** of the inner elongated body (Figures 3-4).

In regards to claim 9, an outer body lumen (between **14** and **24**) is in fluid communication with the lumen of the expandable structure such that insertion of a filling material (fluid) into the outer body lumen passes into the lumen of the expandable structure to expand the expandable structure (Figure 3).

In regards to claim 11, the inner elongated body has an open distal end **22** configured to prevent movement of the stylet **30** therethrough, the open distal end in communication with an inner body lumen of the inner elongated body such that a substance introduced into a proximal opening of the inner body (near **40**) passes

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through the inner body lumen and out of the distal opening (proximal to **32**) of the inner body.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 3 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Fogarty et al.** (U.S. Patent No. **4,483,340**).

Fogarty et al. do not expressly disclose the stylet being made of stainless steel. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the substantially rigid stylet of Fogarty et al. by making it from stainless steel material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use.

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11. Claims 10 and 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Heller et al.** (U.S. Patent No. **5,954,728**) in view of **Fogarty et al.** (U.S. Patent No. **4,483,340**).

Heller et al. disclose a catheter body defining an outer body **18** and an inner body **2**, an expandable structure **3** being disposed on a distal portion of both the outer and inner body (Figure 7), the expandable structure having sufficient strength to compact cancellous bone, a filling material comprising bone cement **4** which is flowable through the outer body lumen into the expandable structure for expansion of the expandable structure (Figure 5). The radially expandable structure **3** expands to a predetermined profile within bone and has a first expandable segment (distal to element **13**) having a larger radius than a second expandable segment (proximal to element **13**), as seen in Figure 5.

Heller et al. lacks a stylet having a proximal end and being sized and shaped for passage through the inner body lumen and adapted to straighten the expandable structure during deployment. The expandable structure **3** appears to have a large profile during deployment, as seen in Figure 8d.

Fogarty et al. teach a stylet **30** adapted to straighten an expandable structure **20** during deployment into an interior body region, the stylet being selectively insertable into and withdrawable from an interior of the expandable structure via the lumen without expanding the expandable structure (Figures 1-4).

It would have been obvious to one of ordinary skill in the art at the time of invention to modify the expandable structure **3** of Heller et al. by having a stylet that is

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selectively engageable to a portion thereof, as taught by Fogarty et al., in order to straighten and reduce the profile of the expandable structure of Heller et al. during deployment.

Response to Arguments

12. Applicant's arguments with respect to claims 1-20 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANE YABUT whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diane Yabut/
Examiner, Art Unit 3734

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3734